JAN 19 2006

510(k) Summary

As required by 21 CFR 807.92(c)

510(k) Number: K052575

Date Prepared: September 16, 2005

Submitter Information:

Submitter's Name/ Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345-2126
Contact Person:	Patrice Stromberg Sr. Regulatory Affairs Specialist Tel: 952-351-1496 Fax: 952-930-9481 pstromberg@sjm.com

Device Information:

Trade Name:	Luminary Cannulator™ Bideflectable Catheter with Lumen
Common Name:	Steerable Catheter
Classification Name:	Steerable Catheter
Class:	Class II, 21 CFR 870.1280

Predicate Devices:

- St. Jude Medical Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen (K040165)
- Medtronic Attain™ Prevail® 6228CTH Steerable Catheter Set (K031211)

Device Description:

The Luminary Cannulator™ Bideflectable Catheter with Lumen is designed for Cardiac Resynchronization Therapy procedures and can be used with St. Jude Medical (SJM) Catheter Delivery Systems.

The Luminary Cannulator™ Bideflectable Catheter with Lumen features two deflectable curves in the catheter tip: a large curve for Coronary Sinus (CS) cannulation and a small curve for venous subselection. The large curve for cannulation comes in Large Curl and Extra Large Curl sizes for a wide range of heart failure patients, including those with enlarged atria. The small curve facilitates subselection of venous branches of the CS.

The Luminary Cannulator™ Bideflectable Catheter with Lumen has an overall length of 108 cm (80 cm working length). The internal lumen of the catheter accommodates up to 0.035" guidewires. The Luminary Cannulator™ Bideflectable Catheter with Lumen has two distal platinum ring electrodes 1 mm in widths, which are spaced 10 mm apart. The bipolar electrode tip configuration provides electrical confirmation of CS access. The distal active tip is manipulated remotely by a control handle with actuator mechanism located at the proximal end of the catheter. An automatic steering lock holds the tip deflection position without the need for an extra locking mechanism.

The proximal handle with deflection actuator contains a hemostasis valve system with sideport and stopcock for aspiration and fluid injection and an electrical connector for sensing of electrical activity and temporary pacing. Valve Bypass Tools, packaged with the Luminary Cannulator™ Bideflectable Catheter with Lumen, are used to direct compatible guidewires through the hemostasis valve from either direction (through the valve, or through distal tip), as well as for forceful manual injection of fluids.

Intended Use/Indications for Use:

The Luminary Cannulator™ Bideflectable Catheter with Lumen is indicated to provide a pathway for delivery and support of transvenous devices and fluids to the Coronary Sinus and coronary vasculature of the heart. The Luminary Cannulator™ Bideflectable Catheter with Lumen can also be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intra-vascular sites when minimizing blood loss is essential.

Summary of Testing

Performance Testing:

To support the expansion of the indications for use, comparison bench testing was conducted with the St. Jude Medical Luminary Cannulator™ Bideflectable Catheter with Lumen and the Medtronic 7F Attain Prevail 6228 CTH Steerable Catheter System. The purpose of the test was to compare the ability of the Luminary Cannulator™ Bideflectable Catheter with Lumen to subselect a branch off the Coronary Sinus or the Great Cardiac Vein with that of the Medtronic Attain Prevail, using a bench model of the human heart. Sub-selection of the branches in the heart model was successful using the Luminary Cannulator™ Bideflectable Catheter with Lumen.

An In-Vivo study of the mechanical performance characteristics of the Luminary Cannulator™ Bideflectable Catheter with Lumen were evaluated in two adult canines. The study evaluated the Luminary Cannulator™ Bideflectable Catheter with Lumen for CS cannulation, subselection of a target branch off the CS / Great Cardiac Vein, and provided analysis of the vessels of the heart through which it passed immediately after the test procedure. Performance of the Luminary

Cannulator™ Bideflectable Catheter with Lumen was satisfactory and met all the study objectives, including the ability to sub-select a branch off the Coronary Sinus or great cardiac vein.

Device integrity testing was performed to support the equivalency of the Luminary Cannulator™ Bideflectable Catheter with Lumen to the predicate devices. Testing included mechanical, functional, and packaging testing. The Luminary Cannulator™ Bideflectable Catheter with Lumen met all specified design and performance requirements.

Biocompatibility. Biocompatibility testing in accordance with ISO 10993 was provided. The material used in the Luminary Cannulator™ Bideflectable Catheter with Lumen has been demonstrated to be biocompatible.

Sterilization Validation: The Luminary Cannulator™ Bideflectable Catheter with Lumen will be sterilized using the existing validated Ethylene Oxide (EtO) sterilization process.

The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use. The Luminary Cannulator™ Bideflectable Catheter with Lumen uses similar technology and has similar intended uses, materials and dimensional characteristics to the predicate devices.

Statement of Equivalence:

Through the data and information presented, St. Jude Medical considers the Luminary Cannulator™ Bideflectable Catheter with Lumen to be substantially equivalent to the St. Jude Medical Reflexion Cannulator™ with Lumen (K040165) and Medtronic Attain™ Prevail® 6228 CTH Steerable Catheter Set (K031211).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

St. Jude Medical
c/o Ms. Patrice Stromberg
Sr. Regulatory Affairs Specialist
14901 De Veau Place
Minnetonka, MN 55345-2126

Re: K052575
Luminary Cannulator™ Bideflectiable Catheter with Lumen
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: II
Product Code: DRA
Dated: December 22, 2005
Received: December 27, 2005

Dear Ms. Stromberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuelmes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K052575

Device Name: Luminary Cannulator™ Bideflectiable Catheter with Lumen

Indications for Use:

The Luminary Cannulator™ Bideflectable Catheter with Lumen is indicated to provide a pathway for delivery and support of transvenous devices and fluids to the coronary sinus and coronary vasculature of the heart. The Luminary Cannulator™ Bideflectable Catheter with Lumen can also be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites when minimizing blood loss is essential.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lodwick

(Division Sign-Off)
Division of Cardiovascular Devices

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